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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,517	06/30/2006	James R. Howard		8067
76809 7590 08/22/2008 Barbara E. Johnson, Esq. 555 Grant Street, Suite 323 Pittsburg, PA 15219				
EXAMINER KASTURI, SRIRAM				
ART UNIT 1612		PAPER NUMBER		
MAIL DATE 08/22/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/562,517

Applicant(s)

HOWARD, JAMES R.

Examiner

SRIRAM KASTURI

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/55/02)
Paper No(s)/Mail Date 4-10-07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-18 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is drawn to mg/kg quantity of L-carnitine, acetyl-L-carnitine, pantothenate and niacinamide per day. But applicant did not specify the kg of what.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicant claims a composition for the treatment of dysfunctional energy metabolism syndrome.

Claims 1-18 are are rejected under 35 U.S.C. 103(a) as being unpatentable over teachings of Howard (US 5,973,004) in view of Hamilton (US 6,479,069 B1).

Howard teaches a composition containing L-carnitine, acetyl-L-carnitine, pantothenic acid or ubiquinone for treating ineffective energy metabolism (Title). Howard also teaches that both pantothenic acid and ubiquinone can also be used in combination with L-carnitine and, acetyl-L-carnitine (Col.18, claim 15, lines 5-7). But Howard's teachings lack use of Niacin. Whereas Hamilton teaches nutritional supplement for increased energy and stamina containing L-carnitine and effective amounts of coenzyme Q which is ubiquinone (Abstract). Hamilton's supplement also contains niacin, pantothenic acid (Col. 9, example1, lines 50 and 54), and acetyl-L-carnitine (Col.12, claim 1b).

One of ordinary skill in the art would be motivated to add niacin in Howard's composition as taught by Hamilton, as Hamilton also teaches an energy supplement. Thus there is an expectation of atleast an additive effect by addition of niacin in Howad's composition. Additionally it would be obvious to one of ordinary skill in the art to arrive at an optimal concentration of niacin for the desired effect.

Howard composition contains L-carnitine, acetyl-L-carnitine, pantothenic acid and ubiquinone and is administered orally or as a parenteral injection in animals and humans for prevention or treatment of syndromes or diseases arising from dysfunctional

energy metabolism (Abstract). Their ratio in mg is at 0.5, 0.5, 0.1 and 0.1 per pound of the body weight of the domesticated mammal or human being treated (Col.17, Claim 2 lines 2-5) which is in the ratio of 1: 1: 0.2 : 0.2 and is with in the range as claimed by applicant (Claim 2). Howard's pharmacological composition contains preservative (Col. 18, claim 8, line 2) and the aqueous solution of the preparation can be administered orally (Claim 16) at a concentration that is pharmacologically effective for treating dysfunctional energy metabolism conditions (Claim 10). Howard teaches use of his preparation as mixed with food or drink or consumed directly (Col.17, lines 10-12), thus suggesting that it can be taken in a concentrate and in a soft drink. Howard teachings include use of the composition in the form of a gelatin capsule (Col. 18, claim 12). Howard teachings include use of the pharmacological preparation for treating dysfunctional energy metabolism comprising cardiomyopathy, epilepsy (Col.17, claim 1, lines 1-5) and seizures (Col.13, lines 62-64).

One of ordinary skill in the art would be motivated to add niacin in Howard's composition as taught by Hamilton, as Hamilton also teaches an energy supplement. Thus there is an expectation of atleast an additive effect by addition of niacin in Howard's composition that can be used in a concentrate, a soft drink. This supplement can be administered orally and parenterally to treat cardiomyopathy and seizures.

Thus there is reasonable expectation of success in combined composition containing L-carnitine, acetyl-L-carnitine, pantothenic acid and niacin for the treatment of dysfunctional energy metabolism syndrome.

Conclusion:

Claims 1-18 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SRIRAM KASTURI whose telephone number is (571)270-5263. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sriram Kasturi/
Examiner
/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612